

# Human Health and Ecological Risk Assessment Training

February 22-26

Brasilia, Brazil

**Summary:** Environmental risk Assessment plays a unique role in serving the needs of various international programs through incorporating, integrating, and coordinating the use of scientific information as a foundation for regulatory decision-making. Risk assessment is an ever-evolving process that significantly impacts human health, food safety, economics, ecological systems, and social decision-making. The United States Environmental Protection Agency (EPA) is a global leader in conducting state-of-the-science risk assessments, and its publications are often the first to apply new risk assessment guidelines, scientific methods, and data. This course will offer training in the primary areas of risk assessment (i.e., hazard identification, dose-response assessment, exposure assessment, and risk characterization). It also will briefly cover risk communication and management concepts because outreach to the public and other stakeholders is essential for the successful implementation of a risk assessment, and ultimately, an environmental decision. This training course will represent the culmination of knowledge-sharing among science experts in the field of human health and ecological risk assessment and exposure assessment. The modules characterizing exposure assessment will be repeated in Session 1 and 2. Case studies demonstrating applications of risk assessment in different settings will also be discussed.

## Day 1: Morning Session (8:00 am to 12:00 pm)

### Joint Human Health and Ecological Risk Assessment Sessions

8:00 am	<p><b><u>Introductions and Brazilian Perspective</u></b></p> <ul style="list-style-type: none"> <li>• Luis Eduardo Pacifici Rangel, Ministry of Agriculture/MAPA, Secretary of Plant and Livestock Defense</li> <li>• Caio Augusto de Almeida, Health Surveillance Agency/ANVISA, General Manager of Toxicology</li> <li>• Karina Cham, Brazilian Environmental Institute/IBAMA, Environmental Analyst</li> <li>• Guilherme Guimarães, Brazilian Crop Protection Association/ANDEF, Regulatory Manager</li> </ul>
8:20 am	<p><b><u>Introduction to Risk Assessment and Risk Assessment Organizations within the EPA</u></b></p> <p>The objective of this course is to provide participants with a basic introduction to the fundamental concepts and terminology associated with risk assessments (e.g., human health, ecological, microbiological). How the risk assessment process is related to and informs risk management policies also will be covered. Examples of how the Federal Government applies the risk assessment paradigm will be provided, including real-world examples of human health and ecological risk assessments. <b>Drs. Allan Davis and Jeff Herrick</b></p>
9:20 am	<p><b><u>Risk Assessment Topics of Interest for Brazil</u></b></p> <p>Discussion of current risk assessment issues faced by organizations located in Brazil. Speakers may include representatives from ANVISA, ANDEF, and IBAMA.</p>
10:00 am	Break

- 10:15 am      **Laws and Regulatory Foundations for Risk Assessment**  
The objective of this course is to provide participants with knowledge of the specific legal and regulatory underpinnings of risk assessment under United States Environmental Protection Agency programs. Specific laws covered include: the Clean Water Act (CWA); the Federal Insecticide, Fungicide and Rodenticide Act, the Federal Food Drug and Cosmetic Act/Food Quality Protection Act (FFDCA/FQPA) and Executive Order 13045. Some State-specific regulatory information also will be briefly covered. **Mr. Ben Harrison, JD**
- 11:15 pm      **Data requirements for pesticides**  
Under FIFRA, a suite of data are required of pesticide registrants. These data define the pesticide's physical, chemical and fate properties, measured residues in crops and environmental matrices as well as the toxicity of the pesticide to humans, non-target organisms (e.g., birds, fish) and plants. This talk will provide a brief overview of the data requirements. **Jeff Dawson, Mike Doherty, Kristina Garber**
- Lunch                      12:00 pm – 1:00 pm**  
**Day 1: Afternoon Session (1:00 pm – 5:00 pm)**  
**Ecological Risk Assessment Session – Ms. Kristina Garber and Dr. Jeff Herrick**
- 1:00 pm      **Overview of Ecological Risk Assessment and Ecological Principles**  
A discussion of general ecological concepts, tools and approaches. An introduction of the fundamentals of ecology and how risk assessment builds off of this. The objectives of this session are to provide participants with knowledge about the fundamentals of ecological risk assessment (such as outlined in the EPA's Guidelines for Ecological Risk Assessment<sup>1</sup>). A brief history of how ecological risk assessment has evolved over time and how it is both similar to and different from human health risk assessment will be presented. How to conduct a well-considered ecological risk assessment will come next with a discussion following four main steps: Problem Formulation, Exposure Characterization, Effects Characterization, and Risk Characterization. Protection goals will be discussed, along with linking assessment and measurement endpoints to those goals.
- 2:30 pm      Break
- 3:00 pm      **Continue discussion of Ecological Risk Assessment**
- 3:30 pm      **Problem Formulation: Starting the Ecological Risk Assessment Process**  
The problem formulation step of ecological risk assessment framework will be covered. Topics include, identification of assessment endpoints, degradates of concern, conceptual model and analysis plans.  
  
*Activity: Conceptual model of pesticides*
- 5:00 pm      **Adjourn**

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<sup>1</sup> Available online at: [http://www.epa.gov/sites/production/files/2014-11/documents/eco\\_risk\\_assessment1998.pdf](http://www.epa.gov/sites/production/files/2014-11/documents/eco_risk_assessment1998.pdf)

## **Day 2: Morning Session (9:00 am – 12:00 pm)**

### **Ecological Risk Assessment Session**

- 9:00 am     **Terrestrial Organism Toxicity Data - Ms. Kristina Garber and Dr. Jeff Herrick**  
This session will provide an overview of standard acute and chronic toxicity studies conducted for terrestrial organisms, including birds, bees and plants. The session will include an overview of study designs, test organisms and endpoints of interest. Discussions will include consideration of study deficiencies and flaws that may impact the validity and utility of a study for ecological risk assessment purposes.
- 10:30 am     Break
- 11:00 am     **Characterization of Effects to Terrestrial Organisms - Ms. Kristina Garber and Dr. Jeff Herrick**  
This session will discuss the integration of available toxicity data from standard toxicity studies and the scientific literature into the effects characterization of a risk assessment. Examples for birds, plants and bees will be used to illustrate the method.
- Lunch        12:00 pm – 1:00 pm**

## **Day 2: Afternoon Session (1:00 pm – 5:00 pm)**

### **Ecological Risk Assessment Session**

- 1:00 pm     **Aquatic Organism Toxicity Data - Ms. Kristina Garber and Dr. Jeff Herrick**  
This session will provide an overview of standard acute and chronic toxicity studies conducted for aquatic organisms, including fish, invertebrates and plants. Methods involving sediment based exposures will also be discussed. The session will include an overview of study designs, test organisms and endpoints of interest. Discussions will include consideration of study deficiencies and flaws that may impact the validity and utility of a study for ecological risk assessment purposes.
- 2:45 pm     Break
- 3:15 pm     **Characterization of effects to aquatic organisms - Ms. Kristina Garber and Dr. Jeff Herrick**  
This session will discuss the integration of available toxicity data from standard toxicity studies and the scientific literature into the effects characterization of a risk assessment. Examples will be used to illustrate the method.
- 5:00 pm     **Adjourn**

**Day 3: Morning Session (9:00 am – 12:00 pm)****Exposure Assessment – Joint Session**

9:00 am      **General Concepts and Approaches for Quantifying Exposure** – Participants will be introduced to the various components of an exposure assessment as well as key terminology. Fundamentals that will be covered include: intake, uptake, and dose; applied, potential, internal, and biologically effective dose; acute, average daily dose, and average lifetime dose; and dermal, oral, and respiratory dose. This course will transition into selecting the approach for quantifying exposure/dose, as well as determining the appropriate type and scope of the study are important first steps in planning an exposure assessment. This course is designed to explore the various approaches that may be used to measure or model exposure, including point-of-contact measurements, scenario evaluation methods, and dose reconstruction approaches. The purpose and utility of these approaches as well as their strengths and weaknesses will be covered. Participants will also be introduced to the types (e.g., deterministic or probabilistic) and scope (e.g., single or multiple chemicals; national-scale, or specific location or industry). The use of exposure descriptors in the exposure assessment planning process will also be discussed.

9:45 am      Break

10:15 am      **Fate and Transport**  
The objective of this module is to give participants an overview of the factors that are important when assessing the fate of contaminants, starting from their point of release until they reach “receptors” (i.e., adults, children, sensitive subpopulations, and other exposure receptors) at the “site of exposure” (a residence mostly). Figures will show potential pathways of movement from source to receptor, and how the ultimate appearance of contaminants in “exposure media” (air, soil, water, food) lead to exposure. The important concept of transfer of contaminants between media - air to soil, soil to plant, water to fish, etc. - will be described. Concepts of partitioning and first order degradation will be presented, and common parameters such as Henry’s Constant, octanol water (or octanol air, or organic carbon, and other) partition coefficients will be defined. The module will conclude with simple paper and calculator exercises on partitioning and first-order decay.

**Lunch                      12:00 pm – 1:00 pm**

**Day 3: Afternoon Session (1:00 pm - 5:00 pm)****Exposure Characterization Specific to Ecology****Ecological Risk Assessment Session - Ms. Kristina Garber and Dr. Jeff Herrick**

1:00 pm      **Current exposure models for terrestrial organisms**  
This session will go through exposure models that are used to assess exposures to birds, mammals, terrestrial-phase amphibians and reptiles, honey bees and plants. This will include T-REX, T-HERPS, BeeREX and TerrPlant<sup>2</sup>. This discussion will also include the higher tier model, TIM.

2:30 pm      Break

3:00 pm      Continue discussions of exposure models.

5:00 pm      **Adjourn**

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<sup>2</sup> For descriptions, see: <http://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment#terrestrial>

## **Day 4: Morning Session (9:00 am – 12:00 pm)**

### **Exposure Assessment – Joint Session - Jeff Dawson, Mike Doherty, Kristina Garber**

**9:00 am      Exposure modeling in water**

EPA's OPP uses simulation models to estimate pesticide concentrations in water that may be consumed by humans as drinking water or may result in exposures to non-target aquatic organisms. This session will provide an overview of the aquatic exposure models<sup>3</sup>.

**9:45 pm      Break**

**10:15 am      Estimating exposures via spray drift transport**

This session will discuss methods for estimating spray drift transport of pesticides. The AgDRIFT<sup>4</sup> model will be discussed.

**11:15 am      Monitoring data**

For many pesticides, monitoring data are available for various media, including water and food. This session will discuss types of monitoring data and how they may be incorporated into the characterization of pesticide exposure to humans and the environment.

**Lunch              12:00 pm – 1:00 pm**

## **Day 4 Afternoon Session (1:00 pm - 5:00 pm)**

### **Ecological Risk Assessment Session - Risk Characterization**

**1:00 pm      Ecological Risk Assessment: Risk Characterization – Ms. Kristina Garber and Dr. Jeff Herrick**

Discussion of ecological effects characterization that describes the types of effects a pesticide can produce in an organism and how those effects change with varying pesticide exposure levels. This session will provide an overview of the method for calculating and interpreting risk quotients, discussion of certainty and uncertainty, weight of evidence and risk conclusions. The concepts associated with tiered risk assessments will also be discussed. Exploration of potential risk mitigation options will also be considered.

**2:45 pm      Break**

**3:15 pm      Case study on risk of pesticides to non-target species – Ms. Kristina Garber and Dr. Jeff Herrick**

Using a case study we will explore risks of pesticides to non-target species such as benthic organisms, birds and bees.

**5:00 pm      Adjourn**

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<sup>3</sup> For a description, go to: <http://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment#aquatic>

<sup>4</sup> For a description, go to: <http://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment#agdrift>

**Day 5: Morning Session (9:00 am – 12:00 pm)**

**Ecological Risk Assessment Session - Ms. Kristina Garber and Dr. Jeff Herrick**

9:00 am     Continue case study discussions

10:30 am   **Break**

11:00 am   Risk communication

A key part of the risk assessment is communication of conclusions with risk managers and stakeholders.

Lunch       12:00 pm – 1:00 pm

**Day 5: Afternoon Session (1:00 pm – 2:30 pm)**

**Joint Session - Discussion, Questions and Answers**

1:00 pm     With Focus On Future Collaboration and Scientific/Regulatory Harmonization

2:00 pm     Wrap up, concluding remarks.

2:30 pm     Adjourn